

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V.,)	
JANSSEN, L.P., and)	
SYNAPTECH, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 05-451-KAJ
)	
PAR PHARMACEUTICAL, INC. and)	
PAR PHARMACEUTICAL)	
COMPANIES, INC.,)	
)	
Defendants.)	

**JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P.,
AND SYNAPTECH, INC.’s REPLY TO COUNTERCLAIMS**

Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, “Janssen”), and Synaptech, Inc. (collectively, “Plaintiffs”), by their attorneys, reply to the Counterclaims of Par Pharmaceutical, Inc. (“Par”),¹ as follows:

1. Paragraphs 1-36 of Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.’s Answer, Affirmative Defenses and Counterclaims are not part of the Counterclaims and require no response by Plaintiffs.
2. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 37, and on that basis deny the allegations set forth therein.
3. In response to Paragraph 38, Plaintiffs admit that Janssen Pharmaceutica N.V. is a wholly-owned subsidiary of Johnson & Johnson, is a corporation organized and

¹ Par Pharmaceutical Companies, Inc. has not joined in the Counterclaims.

existing under the laws of Belgium, and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

4. In response to Paragraph 39, Plaintiffs admit that Janssen, L.P. is a wholly-owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey, and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

5. In response to Paragraph 40, Plaintiffs admit that Synaptech, Inc. (“Synaptech”) is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

6. In response to Paragraph 41, Plaintiffs admit that Par has filed counterclaims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but deny that Par has stated a claim upon which relief may be granted.

7. Plaintiffs admit the allegations of Paragraph 42.

8. Plaintiffs admit the allegations of Paragraph 43.

9. In response to Paragraph 44, Plaintiffs admit that there is an actual and justiciable controversy between the parties as to the infringement and validity of the ‘318 patent. Plaintiffs deny the remaining allegations of Paragraph 44.

10. In response to Paragraph 45, Plaintiffs admit that Janssen, L.P. is the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in doses of

Eq. 4 mg base, 8mg base, and 12 mg base. Plaintiffs deny the remaining allegations of Paragraph 45.

11. The first two sentences of Paragraph 46 contain legal conclusions that require no response by Plaintiffs. In response to the remainder of Paragraph 46, Plaintiffs admit that Janssen, L.P. or its predecessor caused the '318 patent to be listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as a patent which claims the drug for which Janssen, L.P. or its predecessor submitted NDA No. 21-169 or which claims a method of using such drug. Plaintiffs further admit that Synaptech is the owner of the '318 patent and that Janssen is the exclusive licensee. Plaintiffs deny the remaining allegations of Paragraph 46.

12. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 47, and on that basis deny the allegations set forth therein. Plaintiffs state that Par has asserted that "Par Pharmaceutical, Inc. submitted its ANDA No. 77-604 to obtain FDA approval to engage in the commercial manufacture, use and sale of 4mg base, 8mg base, and 12 mg base galantamine hydrobromide tablets, prior to the expiration of the '318 patent." Plaintiffs further admit that Par has asserted that its ANDA contained a paragraph IV certification asserting that the '318 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the product described in Par's ANDA. Plaintiffs deny the remaining allegations of Paragraph 47.

13. In response to Paragraph 48, Plaintiffs admit that notice letters dated May 17, 2005 were received, which contain Par's assertions concerning the '318 patent. Plaintiffs deny the remaining allegations of Paragraph 48.

14. Plaintiffs admit the allegations of Paragraph 49.

15. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 50, and on that basis deny the allegations set forth therein.

16. In response to Paragraph 51, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

17. Plaintiffs deny the allegations of Paragraph 52.

18. In response to Paragraph 53, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

19. Plaintiffs deny the allegations of Paragraph 54.

20. Plaintiffs deny that Par is entitled to any of the relief it has requested.

21. Any allegation not specifically admitted is denied.

Affirmative Defense

22. Par's Counterclaims are barred in whole or in part because they fail to state a cause of action upon which relief may be granted.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

- A. A judgment dismissing with prejudice Par's Counterclaims and each and every Prayer for Relief contained therein;
- B. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- C. An award of costs and expenses of Plaintiffs in defending these Counterclaims;
- D. A judgment including each and every Prayer for Relief sought by Plaintiffs in the Complaint; and
- E. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES

/s/ John G. Day

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Dated: August 8, 2005

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CERTIFICATE OF SERVICE

I hereby certify that on the 8th day of August, 2005, the attached **JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., AND SYNAPTECH, INC.'s REPLY TO COUNTERCLAIMS** was served upon the below-named counsel of record at the address and in the manner indicated:

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VIA FEDERAL EXPRESS

/s/ John G. Day

John G. Day